Filing Date: February 25, 2004

Title: ADVANCED PATIENT AND MEDICATION THERAPY MANAGEMENT SYSTEM AND METHOD

#### REMARKS

This responds to the Advisory Action dated August 28, 2008 and the Final Office Action dated June 11, 2008. Claims 1, 9, 11, 24, and 25 are amended. Claim 12 is currently canceled. Claim 15 was canceled previously. No claims are added. As a result, claims 1-11, 13, 14, and 16-28 are now pending in this application.

Applicant respectfully submits that the amendments and additions to the claims are fully supported by the specification, as originally filed, and that no new matter has been added. Support for the amendments can be found throughout the as-filed specification, for instance, at page 6, lines 15-18. Applicant hereby respectfully requests further examination and reconsideration of the application in view of the following remarks.

#### \$102 Rejection of the Claims

Claims 9-14 and 16-23 were rejected under 35 U.S.C. § 102(b) for anticipation by Yarin et al. (U.S. Patent No. 6,294,999). In view of at least the foregoing amendment and the following remarks, Applicant respectfully traverses this rejection.

Applicant cannot find each and every recitation in claims 9-14 and 16-23 in Yarin et al. For instance, Applicant cannot find in Yarin et al. "an implantable medical measurement device for implantably electrically measuring data related to at least one patient physiological health factor including fluid retention data", as recited in amended claim 9.

The Office Action at page 9 contends that Yarin et al. includes "Smart Trav (i.e. medication therapy management device) communicating with various appliances (i.e. medical measurement device) including but not limited to ... weight scales ... (i.e. fluid retention data)." A weight scale, as mentioned in Yarin et al., would not appear to electrically measure data related to at least one patient physiological health factor including fluid retention data, as essentially recited in claim 9. Furthermore, a weight scale is not implantable nor does it implantably electrically measure data related to at least one patient physiological health factor including fluid retention data. For at least these reasons, Applicant respectfully submits that Yarin et al. is defective in that Yarin et al. does not show each and every recitation of claim 9.

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Dependent claims 10-14 and 16-23 depend from independent claim 9. Accordingly, claims 10-14 and 16-23 incorporate the features of claim 9. For reasons analogous to those stated above with respect to claim 9, claims 10-14 and 16-23 are accordingly believed to be patentable. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable.

For at least these reasons, Applicant submits that claims 9-14 and 16-23 are allowable over Yarin et al. and respectfully requests reconsideration and withdrawal of this rejection.

## §103 Rejection of the Claims

Claims 1-8 and 24-28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Yarin et al. in view of Ellinwood, Jr. (U.S. Patent No. 3,923,060). In view of the foregoing amendment and the following remarks, Applicant respectfully traverses this rejection.

Applicant respectfully submits that obviousness does not presently exist because the references, in combination with the reasoning of the Office Action, do not appear to fully encompass the subject matter of claims 1-8 and 24-28. For instance, Applicant cannot find in the references, in combination with the reasoning set forth in the Office Action:

- · "an implantable device configured to implantably electrically monitor fluid retention", as recited in amended claim 1; and
- · "implantably electrically sensing fluid retention data", as recited in amended claim 24.

Applicant cannot find in the references, in combination with the reasoning set forth in the Office Action, an implantable device configured to implantably electrically monitor fluid retention or a health management host system configured to generate a diuretic medication therapy regimen using the analysis of the patient physiological data (including the fluid retention data) and the medication event data. For reasons similar to those stated above, Applicant can find no mention in Yarin et al. of implantable devices that implantably electrically monitor fluid retention or of using such data to generate a diuretic medication therapy regimen. Additionally, Applicant cannot find in Ellinwood, Jr. any description regarding implantable devices that implantably electrically monitor fluid retention or of using such data to generate a diuretic medication therapy regimen. Ellinwood, Jr. states that "a suitable chemical level sensor 60 is

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employed and which, for example, may sense pH changes, ionic changes, glucose level or other body chemistry factors susceptible to sensing." (Ellinwood, Jr. at col. 9, lines 21-24.) Applicant submits that monitoring fluid retention is not a chemical property as described in Ellinwood, Jr. as being monitored. Moreover, Applicant can find no description in Ellinwood, Jr. regarding electrical monitoring of fluid retention, as essentially recited in claims 1 and 24. As such, Applicant cannot find in the references, in combination with the reasoning set forth in the Office Action, an implantable device configured to electrically monitor fluid retention or a health management host system configured to generate a diuretic medication therapy regimen using the analysis of the patient physiological data (including the fluid retention data) and the medication event data. The Advisory Action states on the Continuation Sheet that the "Examiner disagrees [with Applicant's arguments] and provides support with the combination of Yarin and Ellinwood, Jr." However, Applicant cannot find any such support for implantable devices that implantably electrically monitor fluid retention or of using such data to generate a diuretic medication therapy regimen, either in the locations cited by the Office Action or elsewhere in the references. For at least this reason, Applicant respectfully submits that the references, in combination with the reasoning set forth in the Office Action, does not show each and every recitation of claims 1 and 24.

Moreover, Applicant submits that the Office Action improperly combines Yarin et al. and Ellinwood, Jr. The Office Action at page 6 contends that "[o]ne of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Yarin with the teachings of Ellinwood with the motivation to provide a self-powered medication dispensing apparatus whose operation is made dependent on evaluation of changes in the sensed data". Applicant asserts that such a rationale falls short of a rationale that would have led an ordinarily skilled artisan to combine selected features from each reference in a way that would have resulted in a product corresponding to the claimed subject matter. See KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1741 (2007).

Applicant submits that reasoning of the Office Action provides no factual basis for combining the Smart Tray of Yarin et al. with the apparatus for implanted self-powered medication dispensing of Ellinwood, Jr. Yarin et al. describes a "system . . . for facilitating effective self-management of medication treatment by patients". (See Yarin et al., col. 5, lines

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23-25.) The Yarin et al. system appears to be an external system that, as the Office Action admits on page 6, lacks an implantable device configured to monitor fluid retention. Ellinwood, Jr., on the other hand, describes "[a]n apparatus for dispensing drugs and other medications within the body [that] is adapted to be entirely implanted and to dispense such substances over a long period of time". (See Ellinwood, Jr., at Abstract.) Applicant submits that there is no factual basis on which to rest this rejection, and that, short of impermissible hindsight reconstruction, there is no reason to combine the external, medication self-management system of Yarin et al. with the sensor of the entirely-implanted drug-dispensing apparatus of Ellinwood, Jr., as suggested by the Office Action.

Dependent claims 2-8 depend from independent claim 1; and dependent claims 25-28 depend from independent claim 24. Accordingly, these claims incorporate the features of one of claims 1 and 24. For reasons analogous to those stated above with respect to claims 1 and 24, claims 2-8 and 25-28 are accordingly believed to be patentable. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable.

For at least these reasons, Applicant submits that claims 1-8 and 24-28 are allowable over the references, in combination with the reasoning set forth in the Office Action, and respectfully requests reconsideration and withdrawal of this rejection.

## RESERVATION OF RIGHTS

In the interest of clarity and brevity, Applicant may not have equally addressed every assertion made in the Office Action, however, this does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any of the present claims, the right to challenge or rebut any asserted factual or legal basis of any of the rejections, the right to swear behind any cited reference such as provided under 37 C.F.R. § 1.131 or otherwise, or the right to assert co-ownership of any cited reference. Applicant does not admit that any of the cited references or any other references of record are relevant to the present claims, or that they constitute prior art. To the extent that any rejection or assertion is based upon the Examiner's personal knowledge, rather than any objective evidence of record as

manifested by a cited prior art reference, Applicant timely objects to such reliance on Official Notice, and reserves all rights to request that the Examiner provide a reference or affidavit in support of such assertion, as required by MPEP § 2144.03. Applicant reserves all rights to pursue any canceled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

# CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 359-3275 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date September 11, 2008

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VITE LANDON

Name

Signature